

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DANA-FARBER CANCER INSTITUTE,
INC.,

Plaintiff

V.

GATEKEEPER PHARMACEUTICALS,
INC.,

Defendant and Third-Party Plaintiff

V.

NOVARTIS INTERNATIONAL
PHARMACEUTICAL LTD.,

Third-Party Defendant

CIVIL ACTION NO. 10-CV-11613-DPW

GATEKEEPER ANSWER and THIRD-PARTY COMPLAINT

Gatekeeper Pharmaceuticals, Inc. (“Gatekeeper”), pursuant to the provisions of the Federal Rules of Civil Procedure, states the following Answer and Demand for Relief in response to the Complaint for Declaratory Judgment filed by Dana-Farber Cancer Institute, Inc. (“Dana-Farber”), and states the following Third-Party Complaint against Novartis International Pharmaceutical Ltd. (“Novartis”), a necessary party in whose absence complete relief cannot be given to Dana-Farber and Gatekeeper.

ANSWER and DEMAND FOR RELIEF

Gatekeeper makes the following response to each numbered paragraph in the Complaint for Declaratory Judgment filed by Dana-Farber:

Introduction

1. Gatekeeper admits that this is an action to establish rights and obligations with respect to the licensing of Patent Rights described in an Option Agreement between Dana-Farber and Gatekeeper. The Patent Rights include but are not limited to a newly discovered compound known as WZ4002. Gatekeeper states that, with the addition of Novartis as a necessary party under Rule 19, this action will establish the rights and obligations of Dana-Farber, Gatekeeper, and Novartis.

Parties

2. Gatekeeper admits the allegations of paragraph 2.

3. Gatekeeper admits the allegations of paragraph 3. Gatekeeper is a start-up company founded by the scientific discoverers of WZ4002, the first inhibitor to be identified that can specifically inhibit the L858R/T790M and exon19deletion/T790M drug resistant mutant forms of the epidermal growth factor receptor. Gatekeeper was founded for the purpose of advancing WZ4002 and derivatives as rapidly as possible for clinical use for the benefit of cancer patients whose cancers are refractory to existing therapies.

Jurisdiction and Venue

4. Gatekeeper admits that this Court has jurisdiction pursuant to 28 U.S.C. §§2201, 2202.

5. Gatekeeper admits that this Court has jurisdiction over the parties, including Novartis as a necessary party, pursuant to 28 U.S.C. §1332(a).

6. Gatekeeper admits that this Court has personal jurisdiction over Gatekeeper, Dana-Farber, and Novartis.

7. Gatekeeper admits that venue is proper in this district.

Facts

8. Gatekeeper lacks knowledge or information concerning the execution or terms of a collaborative research agreement between Novartis and Dana-Farber. Gatekeeper states that the assertion by Dana-Farber of restrictions on Dana-Farber as a result of an agreement between Dana-Farber and Novartis means that Novartis is a necessary party.

9. Gatekeeper lacks knowledge or information concerning the allegations of paragraph 9.

10. Gatekeeper lacks knowledge or information concerning the allegations of paragraph 10. Gatekeeper denies that the discovery of WZ4002 was part of any research project funded by Novartis.

11. Gatekeeper lacks knowledge or information concerning the allegations of paragraph 11. Gatekeeper denies that the discovery of WZ4002 was part of any research project funded by Novartis.

The WZ4002 Invention

12. Gatekeeper states that WZ4002 was discovered through a collaboration of Dana-Farber scientists and their laboratories. Gatekeeper denies that funds were provided by Novartis for the discovery of WZ4002. Gatekeeper states that Dana-Farber filed a patent application on or about May 5, 2009 which includes but is not limited to WZ4002 (“the Patent Application”).

The Gatekeeper Option Agreement

13. Gatekeeper states that in the spring of 2009 there were discussions with Dana-Farber concerning licensing the Patent Rights covered by the Patent Application. Gatekeeper states that, as a result of those discussions, Gatekeeper was established, after which Gatekeeper

and Dana-Farber entered into the Option Agreement, effective as of June 1, 2009. A copy of the Option Agreement is attached as Exhibit A.

14. Gatekeeper states that Dana-Farber reviewed and investigated the work and funding that led to the WZ4002 discovery and to the Patent Application before signing the Option Agreement. Gatekeeper states that Dana-Farber supported Gatekeeper's SBIR Phase 1 application to the National Institute of Health. A copy of Dana-Farber's letter to NIH is attached as Exhibit B. Gatekeeper states that Dana-Farber was aware that Dr. Gray had had some funding from Novartis for other work. Gatekeeper states that Dana-Farber entered into the Option Agreement only after determining that Dana-Farber had the legal right and authority to enter into the Option Agreement.

15. Gatekeeper states that Dana-Farber granted Gatekeeper an exclusive option to enter into an exclusive license to the Patent Rights, as described in the Option Agreement.

16. Gatekeeper admits the allegations of paragraph 16. Gatekeeper states that Gatekeeper exercised the option within the 12-month period after raising \$250,000 of financing.

17. Gatekeeper admits the allegations of paragraph 17. Gatekeeper states that it was in the process of negotiating diligently and in good faith with Dana-Farber when Dana-Farber filed this Complaint for Declaratory Judgment.

18. Gatekeeper admits the allegations of paragraph 18. Gatekeeper states that it considers the filing of this Complaint for Declaratory Judgment to be a continuation of good faith efforts by Dana-Farber, and believes that Dana-Farber, upon a declaration of the rights and obligations under the Option Agreement, will issue the license as provided in the Option Agreement.

19. Dana-Farber admits the allegations of paragraph 19.

Novartis Assertion Of Rights To An Option On WZ4002

20. Gatekeeper is uncertain when Novartis learned of the WZ4002 invention.

Gatekeeper admits that an article concerning WZ4002 was published in Nature, and further states that the article listed the funding sources used in the discovery of WZ4002, which did not include any funding from Novartis. Gatekeeper states that Dana-Farber and Novartis received copies of the article before publication.

21. Gatekeeper does not know when, or in what manner, Dana-Farber was informed that Novartis was asserting a right to a license to WZ4002 intellectual property. Gatekeeper does not know the grounds asserted by Novartis to Dana-Farber. Gatekeeper states that Dana-Farber had an external review conducted of the work that resulted in the discovery of WZ4002 and that resulted in the Patent Application and the Option Agreement. Gatekeeper states that the external reviewer advised Dana-Farber on March 10, 2010 that the work “cannot in any reasonable view be asserted to be owned by Novartis.” Gatekeeper otherwise denies the allegations of paragraph 21.

22. Gatekeeper does not know what notice Novartis gave to Dana-Farber, and otherwise lacks knowledge or information sufficient to form a belief to respond to the allegations of paragraph 22.

Gatekeeper Seeks To Exercise Its Option

23. Gatekeeper admits that on or about April 23, 2010, Gatekeeper sent notice to Dana-Farber that Gatekeeper was exercising the option in the Option Agreement for the exclusive license to the Patent Rights. Gatekeeper states that it had relied on the Option Agreement, and had started work in accordance with the Option Agreement.

24. Gatekeeper admits that on or about April 23, 2010, Gatekeeper sent notice to Dana-Farber that Gatekeeper had raised the requisite financing and was exercising the option in the Option Agreement for the exclusive license to the Patent Rights.

25. Gatekeeper admits that Gatekeeper gave Dana-Farber a draft license agreement for the Patent Rights as described in the Option Agreement. The draft license agreement speaks for itself.

26. Gatekeeper admits that Gatekeeper gave Dana-Farber a draft license agreement for the Patent Rights as described in the Option Agreement. The draft license agreement speaks for itself.

Dana-Farber Determination

27. Gatekeeper does not know what claims to the Patent Rights were made by Novartis, or what efforts, if any, were made by Dana-Farber to determine a compromise solution, and therefore lacks knowledge or information sufficient to form a belief to respond to the allegations of paragraph 27.

28. Gatekeeper does not know what additional internal review was undertaken by Dana-Farber with respect to the Patent Rights, and therefore lacks knowledge or information sufficient to form a belief to respond to the allegations of paragraph 28.

29. Gatekeeper states that it requested, and was not given, a copy of the alleged additional internal review. Gatekeeper admits that Dana-Farber stated to Gatekeeper that Dana-Farber believed it lacked the capacity to grant the license of Patent Rights despite the negotiation and execution of the Option Agreement a year earlier. Gatekeeper otherwise denies the allegations of paragraph 29.

30. Gatekeeper asserts that the discovery of WZ4002 was conducted without the use of funds supplied by Novartis; that Dana-Farber entered into the Option Agreement after full and complete due diligence by Dana-Farber; and that Gatekeeper is entitled to the exclusive license of Patent Rights from Dana-Farber in accordance with the Option Agreement.

COUNT I

31. Gatekeeper repeats and incorporates by reference Gatekeeper's responses to the allegations of paragraphs 1 through 30.

32. Gatekeeper states that an actual controversy exists between Dana-Farber, Gatekeeper, and Novartis concerning the rights and obligations of Dana-Farber, Gatekeeper, and Novartis in connection with the Patent Rights including but not limited to rights in WZ4002 and the Gatekeeper Option Agreement.

Demand for Relief

Gatekeeper respectfully requests that:

A. This Court declare and adjudge that the discovery of WZ4002 was not made using funds provided by Novartis and that the Option Agreement is a valid contract between Gatekeeper and Dana-Farber.

B. This Court order Dana-Farber to issue the exclusive license of the Patent Rights in accordance with the terms of the Option Agreement;

C. This Court determine the damages sustained by Gatekeeper as a result of the delay in issuance of the license, and enter judgment against Dana-Farber for those damages, together with interest and costs;

D. This Court order Dana-Farber to pay the costs and expenses of Gatekeeper incurred in this litigation; and

E. This Court enter such further order as is necessary and just.

THIRD PARTY COMPLAINT FOR DECLARATORY JUDGMENT

Introduction

This is a third party complaint against Novartis International Pharmaceutical Ltd. (“Novartis”) which has asserted claims in connection certain Patent Rights, including but not limited to a newly discovered compound known as WZ4002. In 2009, Dana-Farber Cancer Institute, Inc. (“Dana-Farber”) contracted to give an exclusive license to the Patent Rights, including but not limited to WZ4002, to Gatekeeper Pharmaceuticals, Inc. (“Gatekeeper”). Novartis subsequently claimed that prior contractual agreements between Novartis and Dana-Farber prevent the issuance of the exclusive license to Gatekeeper. Dana-Farber filed this action seeking a declaratory judgment concerning the rights and obligations of Gatekeeper and Dana-Farber in connection with the Patent Rights. Novartis is a necessary party to this action.

Parties

1. The third party plaintiff Gatekeeper Pharmaceuticals, Inc. (“Gatekeeper”) is a Delaware corporation with a principal place of business in California. Gatekeeper is a start-up company founded by the scientific discovers of WZ4002, the first inhibitor to be identified that can specifically inhibit the L858R/T790M and exon19deletion/T790M drug resistant mutant forms of the epidermal growth factor receptor. Gatekeeper was founded for the purpose of advancing WZ4002 and derivatives as rapidly as possible for clinical use for the benefit of cancer patients whose cancers are refractory to existing therapies.

2. Novartis International Pharmaceuticals Ltd. (“Novartis”) is a corporation duly organized under the laws of a country other than the United States.

Jurisdiction and Venue

3. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§2201 and 2202 because Gatekeeper seeks declaratory relief with respect to an actual controversy that exists between Gatekeeper and Novartis.

4. This Court has jurisdiction over these parties pursuant to 28 U.S.C. §1332(a) because the case concerns citizens of different states and the controversy exceeds the sum or value of \$75,000.

5. This Court has personal jurisdiction over Novartis pursuant to G.L. c.223A, §3 because Novartis conducts business in Massachusetts, maintains necessary contacts with Massachusetts, and the issues arise out of acts that occurred within Massachusetts.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391 because Gatekeeper and Novartis conduct business in this district, and because the acts giving rise to this third party complaint occurred in the district.

Facts

7. WZ4002 was discovered through a collaboration of work by Dana-Farber scientists and their laboratories. Dana-Farber then filed a patent application, and by an option agreement effective June 1, 2009 (the “Option Agreement”), granted Gatekeeper an exclusive option to enter into an exclusive license of the Patent Rights under Dana-Farber’s patent application. The Patent Rights are defined in the Option Agreement, and include but are not limited to WZ4002. Gatekeeper relied on the Option Agreement, began the process to research and develop the Patent Rights, and raised funds.

8. On or about April 23, 2010, Gatekeeper exercised its option as provided in the Option Agreement. Gatekeeper and Dana-Farber then entered into good faith negotiations for the exclusive license of the Patent Rights. During those negotiations, Dana-Farber stated that Novartis had asserted rights to a license to the WZ4002 intellectual property. Dana-Farber maintained that, because of the assertion by Novartis, Dana-Farber could not give the license to Gatekeeper. Dana-Farber then filed the complaint for declaratory judgment to determine the rights and obligations of Dana-Farber and Gatekeeper. Although Novartis is a necessary party to the determination, Dana-Farber did not include Novartis as a party.

9. Gatekeeper maintains that the discovery of WZ4002 was not made with funds provided by Novartis, that Novartis has no claim to WZ4002 or to the Patent Rights, and that Dana-Farber should issue the exclusive license of the Patent Rights to Gatekeeper in accordance with the Option Agreement.

10. Novartis claims that WZ4002 was discovered using funds provided by Novartis, that Novartis has the exclusive right to any license of WZ4002, and that Dana-Farber may not issue a license to Gatekeeper for the Patent Rights.

11. An actual controversy exists between Gatekeeper and Novartis concerning the rights of Gatekeeper to a license for the Patent Rights.

Demand for Relief

Gatekeeper respectfully requests that:

A. This Court declare and adjudge that the discovery of WZ4002 was not made using funds provided by Novartis, that Novartis has no rights in the Patent Rights including but not limited to WZ4002, that the Option Agreement is a valid contract between Gatekeeper and Dana-

Farber, and that Dana-Farber should issue a license for the Patent Rights in accordance with the Option Agreement;

B. This Court determine the damages sustained by Gatekeeper as a result of the delay in issuance of the exclusive license occasioned by the assertion of a claim by Novartis, and enter judgment for that amount against Novartis, together with interest and costs;

C. This Court order Novartis to pay the costs and expenses of Gatekeeper included in this litigation; and

D. This Court enter such further order as is necessary and just.

GATEKEEPER PHARMACEUTICALS,
INC.,

By its attorney,

/s/ John O. Mirick

John O. Mirick, Esq.

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Dated: October 15, 2010

CERTIFICATE OF SERVICE

I, John O. Mirick, hereby certify that this document(s), filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 15, 2010.

/s/ John O. Mirick
John O. Mirick, Esq.